ARIZONA DEPARTMENT OF HEALTH SERVICES

# Recommendations for Residential Healthcare Facility Diagnostic Testing

Diagnostic tests check samples from the respiratory system, such as a swab from the inside of the nose, to see if someone is currently infected with SARS-CoV-2, the virus that causes COVID-19. Some tests are point-of-care (POC) tests, meaning results may be available at the testing site in less than an hour. Other tests must be sent to a laboratory to analyze, a process that may take 3–5 days once received by the lab.

The Centers for Disease Control and Prevention (CDC) recommends diagnostic testing for:

- Individuals with signs or symptoms consistent with COVID-19.
- Asymptomatic individuals with recent known or suspected exposure to SARS-CoV-2 to control transmission.
- Asymptomatic individuals without known or suspected exposure to SARS-CoV-2 for early identification in special settings.
    - Certain settings, such as residential healthcare facilities, can experience rapid spread of SARS-CoV-2 due to vulnerable populations being in close quarters for extended periods of time.

The sections below provide recommendations on testing methods and procedures for residential healthcare facilities ("residential facilities").

**Type of Test Recommended**

- A diagnostic test for SARS-CoV-2, including:
    - Polymerase Chain Reaction (PCR)
    - Antigen
- Antibody/serology tests are not diagnostic, so they are not recommended for screening for current infection.

**Recommended Test Use**

- As needed, when individuals have signs or symptoms consistent with COVID-19 or recent known or suspected exposure to SARS-CoV-2.
- Visitor screening.
- Could consider routine staff screening (e.g., monthly).

**Planning for Specimen Collection, Testing, and Data Management**

- Establish a plan that outlines who is responsible for performing specimen collection from staff and residents, a process for specimen collection and transport (if needed), and who is responsible for conducting POC testing.
    - Consider what facility staff can collect specimens on themselves/from other staff or whether additional support is needed for specimen collection (i.e., specimen collection contractor). The facility's staff may need to be trained to collect

specimens correctly. Training should include infection prevention and control requirements and correct personal protective equipment (PPE) use.
    - Determine whether staff can be tested at the facility or if they will be tested off-site.
        - Develop an informed consent process to ensure the facility can receive results.
        - Facility policies and procedures should be referenced for staff refusing to be tested.
    - Determine how results will be shared with the facility, the Arizona Department of Health Services (ADHS), and the local health department.
    - Determine a process that captures which individuals were tested or were unable to be tested.

**Coordinating Reporting of Testing Results**

- For off-site testing, laboratories that can quickly process large numbers of tests with rapid reporting of results (e.g., within 48 hours) should be selected for testing intended to inform facility infection prevention initiatives to prevent and limit transmission.
    - Ideally, one laboratory should be selected to process specimens to facilitate data collection and analysis.
- Report positive and negative results of on-site COVID-19 testing (e.g., antigen testing) directly to ADHS pursuant to Executive Order 2020-37. There are two methods for reporting these results to ADHS:
    - The preferred method is to register your facility with this Google Form. Once registered, you will receive another link to enter reports into a separate Google Form. A guidance document on this process is available on the Lab Resources webpage.
    - The second option is to follow the flat file reporting requirements outlined on the Lab Resources webpage. If files are not submitted in the proper format, you will be required to resubmit the file in the appropriate format.
- Ensure COVID-19 positive results and suspected outbreaks are reported to the local health department pursuant to Arizona Administrative Code R9-6-202.
    - Submit a report within 24 hours after a case or suspect case is diagnosed, treated, or detected or an occurrence is detected.
    - Submit a report within 24 hours after detecting an outbreak of Respiratory Disease in a Health Care Institution.
- The facility should maintain records of staff who have positive tests.
- Testing should be carried out in a way that protects confidentiality to the extent possible and is consistent with applicable laws and regulations.
- When employers become aware of cases, the Recordkeeping and Reporting Occupational Injuries and Illness standard (29 CFR 1904), requires certain employers to keep a record of serious work-related injuries and illnesses including work-related COVID-19.

**Recommendations for Conducting Swabbing**

General considerations

- Follow CDC's Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19)
- The number of people present during specimen collection should be limited to only those essential for care and procedure support.
    - Visitors or other bystanders should not be present for specimen collection.
- Swabbing of multiple individuals should not be performed in the same room at the same time, unless appropriate separation between swabbing stations can be maintained.

Consider if self-collection is appropriate

- Some diagnostic tests use samples that are self-collected, such as saliva and nasal swabs.
- PPE use can be minimized through self-collection while staff remain at least 6 feet away from the individual being swabbed.
- Nasal Swabs: The individual must be able to correctly self-swab and place the swab in transport media or sterile transport device and seal.
    - If the individual needs assistance, assistance can be provided by placing the swab into transport media or a sterile transport device and sealing it for them.
- If bulk-packaged swabs are used for sample collection, care must be exercised to avoid contamination of any of the swabs in the bulk-packaged container.

Location of specimen collection

- Ideally, specimen collection should be performed one individual at a time in a room with the door closed and no other individuals present. If individual rooms are not available, other options include:
    - Large spaces (e.g., gymnasiums) where sufficient space can be maintained between swabbing stations (e.g., greater than 6 feet apart).
    - An outdoor location, weather permitting, where other individuals will not come near the specimen collection activity.
- Considerations for multiple individuals being swabbed in succession in a single room:
    - Consider the use of portable HEPA filters to increase air exchanges and to expedite removing infectious particles.
    - Minimize the amount of time the individuals will spend in the room. Individuals awaiting swabbing should not wait in the room where swabbing is being done. Those swabbed should have a face mask or cloth cover in place for source control throughout the process, only removing it during swabbing.
- Minimize the equipment kept in the specimen collection area. Consider having each person bring their own prefilled specimen bag containing a swab and labeled sterile viral transport media container into the testing area from the check-in area.

PPE for swabbing

- Staff in the room or specimen collection area should wear an N95 or higher-level respirator (or surgical mask if a respirator is not available) and eye protection. A single pair of gloves and a gown should also be worn for specimen collection or if contact with contaminated surfaces is anticipated.
    - If respirators are not readily available, they should be prioritized for other procedures at higher risk for producing infectious aerosols (e.g., intubation), instead of for collecting nasopharyngeal specimens.

- Extended use of respirators (or surgical masks) and eye protection is permitted. However, care must be taken to avoid touching the necessary face and eye protection. If extended use equipment becomes damaged, soiled, or hard to breathe or see through, it should be replaced. Hand hygiene should be performed before and after manipulating PPE.
- Gloves should be changed and hand hygiene performed between each person being swabbed.
- Gowns should be changed when there is more than minimal contact with the person or their environment. The same gown may be worn for swabbing more than one person provided the staff collecting the test minimizes contact with the person being swabbed. Gowns should be changed if they become soiled.
- Consider having an observer who does not engage in specimen collection but monitors for breaches in PPE use throughout the specimen collection process.
- Staff who are handling specimens, but are not directly involved in collection (e.g., self-collection) and not working within 6 feet of the individual being tested, should follow Standard Precautions; gloves are recommended, as well as a surgical mask or face mask for source control.

Cleaning and disinfection between individuals

- Surfaces within 6 feet of where specimen collection was performed should be cleaned and disinfected using an Environmental Protection Agency-registered disinfectant from List N if visibly soiled and at least hourly.
- Terminal cleaning and disinfection of all surfaces and equipment in the specimen collection area should take place at the end of each day. Resident rooms should be cleaned and disinfected in accordance with Implementing Environmental Infection Control in the Interim Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed Coronavirus Disease 2019 (COVID-19) in Healthcare Settings.
- Used testing cassettes and collection swabs should be disposed of in a biohazard container.

**Considerations for Use of Antigen Testing in Residential Facilities**

When to consider confirmatory PCR after antigen test results

As the sensitivity of antigen tests is generally lower than PCR, FDA EUA recommends that negative POC antigen tests be considered presumptive. Clinical staff in residential facilities should consider when confirmatory PCR testing might be needed (see nursing home example for applicable guidance) prior to making clinical decisions, cohorting residents, or excluding staff from work. When interpreting the results of antigen tests, test characteristics and probability of infection should be considered.

- Test sensitivity might vary between antigen testing platforms. Facilities should be aware of which platform is being used and the sensitivity of the test for the patient population to be tested. For example, the first two antigen tests that have received FDA EUAs range in sensitivity from 84% to 97% when used within 5 days of symptom onset.
- Factors that increase the probability of infection include the presence of symptoms in the person being tested, recent exposure to someone diagnosed with COVID-19, and whether testing is being conducted in a facility with an outbreak or within a

high-prevalence community. These factors inform the decision of whether confirmatory testing by PCR is indicated following an antigen test.

If a confirmatory PCR test is performed within 48 hours, individuals should be assumed infectious until the confirmatory test results are completed.

*Example 1*: If a symptomatic resident tests presumptive negative on antigen test and a PCR is performed, the resident should remain on Standard, Contact, and Droplet precautions until the PCR test results.

- If PCR positive (false negative antigen result), then the resident should remain on precautions until no longer infectious.
- If PCR negative (true negative antigen result), then the resident can discontinue precautions.

*Example 2*: If an asymptomatic staff working in a residential facility without an outbreak in a county with low community prevalence tests antigen positive and a PCR is performed, they should be excluded from work until a negative PCR test is available.

- If PCR positive (true positive antigen result), then the staff should remain at home until no longer infectious.
- If PCR negative (false positive antigen result), then the staff can discontinue precautions.

CDC and ADHS **do not** recommend a test-based strategy to discontinue isolation.

Uses of antigen testing in residential facilities

- Testing of symptomatic residents and staff,
- Testing of asymptomatic residents and staff in facilities as part of an COVID-19 outbreak response, and
- Testing of asymptomatic staff in facilities without a COVID-19 outbreak.

Testing in other circumstances are likely to occur, such as testing asymptomatic residents and staff who were exposed to persons with COVID-19 outside of the facility (e.g., recent hospitalization or outpatient services) or through other screening activities. The principles described here can be used to guide the interpretation of antigen test results in those situations.

Antigen tests should not be utilized to determine the duration of isolation precautions nor when staff can return to work.

Considerations for when performing testing

- Before beginning testing, read and become familiar with the instrument manufacturer's instructions/package insert (abbreviated to IFU), and user manual if included.
    - Be familiar with the timing of the tests. Most antigen tests need to either sit for 15 minutes before being read or must be read within a specified window or they will not be valid. This information can be found in the package insert instructions.
- Quality control (QC) must also be performed before testing and should be based on the manufacturer's recommendations.
    - If issues are noted with the QC, or it does not pass, contact the instrument manufacturer technical support.
- Before testing, it is recommended to have all supplies on hand, including a timer, sharpie or other marker that can write on the testing kits to label samples, a spreadsheet or

similar form to document the results, and a biohazard disposal to discard used testing cassettes and collection swabs.
- If collecting samples before immediate testing, ensure samples are properly labeled with patient identifying information.

<u>Considerations for interpreting antigen test results in residential facilities</u>

*Testing of symptomatic residents and staff*
- If an antigen test is positive, no confirmatory test is necessary.
    - Residents should be placed in isolation precautions, and staff should be excluded from work.
    - If the resident or staff is the first positive test for SARS-CoV-2 within the facility (i.e., an index case), an outbreak response should be initiated immediately.*
- If an antigen test is presumptive negative, perform PCR immediately (e.g., within 48 hours).
    - Symptomatic residents and staff should be kept in isolation precautions or excluded from work until PCR results return.
    - Some antigen platforms have higher sensitivity when testing individuals within 5 days of symptom onset. Clinical discretion should be utilized to determine if individuals who test negative on such platforms should be retested with PCR.
    - Note: if an individual has recovered from SARS-CoV-2 infection in the past 3 months and develops new symptoms suggestive of COVID-19, alternative diagnoses should be considered prior to retesting for SARS-CoV-2.

*Testing of asymptomatic residents or staff in facilities as part of an outbreak response**
- If an antigen test is positive, no confirmatory test is necessary.
    - Residents should be placed in isolation precautions, and staff should be excluded from work.
- If an antigen test is presumptive negative, residents should be placed in appropriate precautions for facilities with an outbreak. Staff should be allowed to continue to work with continued symptom monitoring. The facility should continue repeat testing (antigen or PCR) every 3–7 days until no new cases are identified for a 14-day period.
- Note: asymptomatic individuals who have recovered from SARS-CoV-2 infection in the past 3 months and live or work in a residential facility performing facility-wide testing should not be tested for SARS-CoV-2.

*Testing of asymptomatic staff or visitors in facilities without an outbreak*
Residential living facilities can consider performing routine visitor (i.e., every visit) and staff screening (e.g., monthly).
- If an antigen test is positive in a visitor, exclude from visitation until they meet criteria for discontinuation of isolation.
- If an antigen test is positive in staff, perform confirmatory PCR test within 48 hours of the antigen test, especially in counties with low prevalence. If a confirmatory test is performed, staff should be excluded from work until confirmatory test results are completed.
    - If the confirmatory test is positive, then exclude the staff from work and initiate an outbreak response including facility-wide testing of all residents and staff.

    - If the confirmatory test is negative, discuss results with the local public health department to determine how to interpret the discordant results and next steps. The incidence of SARS-CoV-2 infection in the local community can help interpret the likelihood of a false positive antigen test. The time between antigen test and PCR test should also be considered. If PCR is performed >48 hours after an antigen test, it is possible that the amount of viral shedding has changed during the time between antigen and PCR and testing. Therefore, the antigen test may indicate a true infection even if the PCR is negative.
- If an antigen test is presumptive negative in staff, allow staff to continue to work. Staff should continue to monitor for symptoms, and repeat testing should continue per CMS recommendations.
- Note: Staff who have recovered from SARS-CoV-2 infection in the past 3 months and are asymptomatic should not be tested for SARS-CoV-2.

*Notes:*
*A COVID-19 outbreak response in a residential facility is triggered when a resident or staff tests positive for SARS-CoV-2. An index infection in a resident should include SARS-CoV-2 infections that originated in the residential facility and should not include:

- Residents who were known to have COVID-19 on admission to the facility and were placed into isolation precautions.
- Residents who were placed into isolation precautions on admission and developed SARS-CoV-2 infection within the 14-day period after admission.

**Table of Considerations for On-site v Off-site Testing**

| | As Needed Testing by Facility (On-site) | As Needed Testing by Laboratory (Off-site) | Routine Testing by Facility (On-site) | Routine Testing by Laboratory (Off-site) |
|---|---|---|---|---|
| **Reason for Testing** | Individuals are symptomatic or have exposure to SARS-CoV-2 | Individuals are symptomatic or have exposure to SARS-CoV-2 | Staff or Visitor Screening | Staff Screening |
| **Type of Test** | Polymerase Chain Reaction (PCR) or Antigen | Polymerase Chain Reaction (PCR) or Antigen | Polymerase Chain Reaction (PCR) or Antigen | Polymerase Chain Reaction (PCR) or Antigen |
| **Prerequisites** | CLIA Certified<br>Obtain point-of-care instrument and kits<br>Get informed consent to receive results | Contract with laboratory and/or specimen collection contractor<br>Get informed consent to receive results | CLIA Certified<br>Obtain point-of-care instrument and kits<br>Get informed consent to receive results | Contract with laboratory and/or specimen collection contractor<br>Get informed consent to receive results |
| **What staff will be tested?** | Determine on a case-by-case basis (e.g., staff with close contact to a known or suspected case: <6 feet for at least 15 minutes) | Determine on a case-by-case basis (e.g., staff with close contact to a known or suspected case: <6 feet for at least 15 minutes) | All staff | All staff |
| **Who is collecting specimens?** | Self-collection or collection by health professional | Self-collection or collection by health professional | Self-collection or collection by health professional | Self-collection or collection by health professional |
| **PPE requirements for self-collection and maintaining at least 6 feet distance** | Gloves and surgical mask | Gloves and surgical mask | Gloves and surgical mask | Gloves and surgical mask |

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|---|---|---|---|---|
| **PPE requirements for health professional performing specimen collection** | Gloves, gown, surgical mask or respirator, and eye protection. | Gloves, gown, surgical mask or respirator, and eye protection. | Gloves, gown, surgical mask or respirator, and eye protection. | Gloves, gown, surgical mask or respirator, and eye protection. |
| **Cleaning and disinfection between on-site specimen collections** | Clean and disinfect surfaces within 6 feet of specimen collection using EPA List N if visibly soiled at least hourly. | Clean and disinfect surfaces within 6 feet of specimen collection using EPA List N if visibly soiled at least hourly. | Clean and disinfect surfaces within 6 feet of specimen collection using EPA List N if visibly soiled at least hourly. | Clean and disinfect surfaces within 6 feet of specimen collection using EPA List N if visibly soiled at least hourly. |
| **Reporting Requirements** | Report positive and negative results to ADHS.<br>Report positive results and suspected outbreaks to local health department. | Report positive results and suspected outbreaks to local health department. | Report positive and negative results to ADHS.<br>Report positive results and suspected outbreaks to local health department. | Report positive results and suspected outbreaks to local health department. |

**Resources**

Abbott BinaxNOW COVID-19 Ag Card

- Package Insert
- Training Materials

BD Veritor System for Rapid Detection of SARS-CoV-2

- Ordering Information
- Package Insert
- Webinar Slides

Quidel Sofia SARS Antigen FIA

- Ordering Information
- Package Insert
- Webinar Slides

HHS Webinar: Antigen Testing in Nursing Homes (September 3, 2020)

- Test manufacturers, BD (view slides) and Quidel (view slides) walk through steps associated with performing the BD Veritor and Quidel Sofia SARS-CoV-2 antigen tests.

ADHS

- Healthcare Providers, Facilities, and Partners
- Laboratory Resources
    - Reporting Guidance for Facilities using Point-of-Care Devices
- Residential Living COVID-19 Guidance
- Release from Isolation and Quarantine Guidance
- BinaxNOW FAQs
- CLIA Information for Point-of-Care Testing

CDC

- Considerations for Preventing Spread of COVID-19 in Assisted Living Facilities
- Considerations for Use of SARS-CoV-2 Antigen Testing in Nursing Homes
- Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19
- Interim Guidance for Rapid Antigen Testing for SARS-CoV-2
- Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)
- Guidance for SARS-CoV-2 Point-of-Care Testing

CMS

- CLIA FAQs

FDA

- Emergency Use Authorizations for Antigen Diagnostic Tests for SARS-CoV-2
- FAQ on screening asymptomatic individuals